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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,607	12/17/2001	Akio Kobayashi	111473	5916

25944 7590 07/13/2004

OLIFF & BERRIDGE, PLC  
P.O. BOX 19928  
ALEXANDRIA, VA 22320

EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/015,607

Applicant(s)

KOBAYASHI ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-15 is/are rejected.
- 7) ☒ Claim(s) 6-8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5 Feb 04, 5 Feb 03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Restriction/ Election***

1. The Office acknowledges the timely receipt of Applicant's Election, dated 26 April 2004, electing Group I, claims 1-15, with traverse. Applicant traverses saying primarily that restriction is improper because the Office has not met the standard of MPEP 803 that there must be a serious burden on the Examiner if restriction is not required. Applicant's traversal is unpersuasive because the election of species requirement groups the living cells according to Animal cell and Plant cells. Plant cells and animal cells have very different component structures, biochemistry, and lifestyles, for example plants have cell walls and animal cells have no cell walls. While the searches for plant cells and animal cells might overlap, these searches would not be identical, and there would constitute undue burden on the Examiner. This restriction is made final.

### ***Status of the Claims***

2. Claims 1-18 drawn to plant cells, are pending, claims 16-18 are withdrawn as being drawn to a nonelected invention, and claims 1-15 are examined in the instant action.

### ***Information Disclosure Statement***

3. Applicant's IDSs filed 5 February 2004, 5 February 2003, 21 June 2002, and 25 April 2002 are acknowledged and signed copies included herewith.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by European Patent Office 0 482 847 A2, published 06 May 1992 (hereafter "EPO '847").

EPO '847 teaches a method for introducing a foreign matter in a cell, comprising placing a small particle carrying a foreign matter at a part of a cell surface of a living cell (p. 3, lines 55-57), boring a hole in the cell wall and/or membrane by irradiating and treating the cell surface with a laser beam (p. 5, line 78) and introducing the foreign matter into the living cells. EPO '847 teaches a barley plant (p. 3, line 50) as the living cell, and the foreign matter introduced is the genetic material plasmid DNA pBI221 (p. 3, lines 56-57).

The language "a small particle carrying a foreign matter at a part of a cell surface of a living cell" is indefinite and is read broadly to mean an aqueous solution containing the "foreign matter" of plasmid DNA pBI221 (p. 3, lines 55-57).

A method of "boring the hole in the cell wall" is inherently a method that involves removing a part of the cell wall, since the cell interior is encased inside a

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cell wall and a cell membrane within the cell wall (Weber, et. al., Manipulation of Cells, Organelles, and Genomes by laser microbeam and optical traps, 1992, International Rev. of Cytology, vol. 133, pages 1-41, p. 17, section A and B).

Accordingly, EPO '847 anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-5, 10-11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPO '847, as discussed above for claims 1-3, 10 and 11, in view of Gad, et. al. (Physiologia Plant. 1990, Vol 79, pages 177-183).

The teachings of EPO '847 are discussed above.

EPO '847 does not teach the use of liposome fusion to introduce DNA in to a living cell.

Gad, et. al. teach the use of a small liposome particle (Gad, et. al., p. 178, last full ¶ in 1<sup>st</sup> column) having a particle diameter of 30-50 nmeters (0.03-0.05 µm) (p. 180, last full ¶), which is in the range of 0.01 µm to 10 µm specified by claimed invention.

It would have been obvious to one of skill in the art, at the time of the invention was made, to modify the invention of EPO '847 in view of Gad et. al. to

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use the a liposome having a particle diameter of 30-50 nmeters as the means of introducing the foreign particle into the laser treated living plant cell, because liposome fusion were known in the art as being successful for introduction of DNA into plant cells (Gad et. al. p. 180, last full ¶). One skilled in the art would have been motivated to so, with a reasonable expectation of success.

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

8. Claims 1-5 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPO '847, in view of Gad, et. al. (Physiologia Plant. 1990, Vol 79, pages 177-183), as discussed above for claims 1-5, 10-11, and 13-15, and further in view of Weber, et. al., (Manipulation of Cells, Organelles, and Genomes by laser microbeam and optical traps, 1992, International Rev. of Cytology, vol. 133, pages 1-41, p. 6, Table 1).

The teachings of EPO '847 and Gad are discussed above.

EPO 847 and Gad et. al. do not teach the use of a laser selected from the group of YAG laser, an exima laser, an Ar ion laser, a nitrogen laser, or a nitrogen-excited color laser, or the use of a microinjector to introduce the foreign DNA into the cell.

Weber (page 6, Table 1) teaches the use and availability of use of a laser selected from the group of YAG laser, an exima laser, an Ar ion laser, a nitrogen laser, or a nitrogen-excited color laser for microbeam injection of DNA in cells. Weber also teaches the introduction of foreign DNA using microinjection by

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micromanipulation with microbeam lasers using an optical trap (p. 11, last full ¶ and ¶ bridging to p. 12).

It would have been prima facie obvious to modify the method of EPO '847 in view of Gad et. al. by using the specific lasers of Weber to introduce DNA into cells and also by using the microinjection by micromanipulation with microbeam lasers of Weber to introduce DNA into living cells.

One skilled in the art would have been motivated to use these lasers for injection of DNA into cells, because the various lasers have different qualities which recommend them for given purposes and materials, this would provide a wider range of use which is desirable, with reasonable expectation of success. One skilled in the art would also be motivated to use the microinjection by micromanipulation to introduce DNA into living cells, because this method has proven success in introducing DNA into living plant cells, with reasonable expectation of success.

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

#### Remarks

9. Claims 1-5 and 9-15 are not allowed, given the prior art of record. Claims 6-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
July 12, 2004



AMY J. NELSON, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600